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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,909	11/16/2001	Joan M. Fallon	8016-5	3427

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,909	FALLON, JOAN M.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 2, and 7 are pending in the present application. In the prior action, mailed on July 29, 2003, claims 1, 2, 7, and 21 were under consideration and rejected, and claims 22-29 were withdrawn as to non-elected inventions. In the Response, properly filed on May 10, 2004, claim 1 was amended; and claims 21-29 were cancelled.

2. Applicant's Response to the Requirement for Information, in the form of replacing Figure 4 of the application with a corrected figure, is noted. The Response is found acceptable.

Drawings

3. **(Prior Requirement-Withdrawn)** In the prior action, New corrected drawings were required in this application because in Figure 2, the figure has misspellings of the work "Parkinson" for both patients 5 and 15. New replacement figures were received on May 10, 2004. These drawings are accepted by the Examiner.

Specification

4. **(Prior Objection-Withdrawn)** The disclosure was objected to because of the following informalities: the specification is objected to because of inconsistencies between the teachings of the specification, and the data presented in Figures 3 and 4. In view of the correction of the data in Figure 4, the objection is withdrawn.

Claim Objections

5. **(Prior Objection-Withdrawn)** Claim 21 was objected to because of the following informalities: the claim limits the method of claim 1 to embodiments wherein "the PPD is autism." In view of the cancellation of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **(Prior Rejection-Withdrawn)** Claims 1, 2, and 7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims were rejected for because, while the claims described methods of determining if a person has a pervasive development disorder (PDD), the application provides no definition for what is included within the class of disorders identified as PDDs. In view of the amendment of the claims, such that they are no longer relate to PDDs generally, the rejection is withdrawn.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Withdrawn)** Claims 1, 2, 7, and 21 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of determining if a person has autism, does not reasonably provide enablement for methods of

determining if a person can develop such a disorder. In view of the amendment of the claims such that they now read only on methods of determining if a person has autism, and not on methods of determining if a person can develop the disorder, the rejection is withdrawn.

10. **(Prior Rejection-Withdrawn)** Claims 1, 2, and 7 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. These claims were rejected because they read on methods of determining if a person has any PDD based on the presence of a plurality of pathogenic infections. However, the Applicant has not provided a clear definition of what a PDD is. In view of the amendment of the claims such that they are no longer relate to PDDs generally, the rejection is withdrawn.

11. **(Prior Rejection- Maintained)** Claims 1, 2, 7, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while apparently being enabling for diagnosing autism, by detecting the presence of antigens from a plurality of pathogens listed, for example, in Figure 3 or on page 9 of the application, does not reasonably provide enablement for methods of such diagnosis by detecting antigens of plurality of other pathogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Because claim 21 has been cancelled from the application, the rejection is withdrawn from this claim.

It is first noted that the Applicant believes it is not reasonable for the Office to interpret the claims as reading on any pathogen. Rather, the applicant argues, one of ordinary skill in the art would read the application as requiring the pathogen to be one that is capable of living in or thriving in the gastrointestinal tract. However, it is not clear from which teachings those in the art

would draw this conclusion. There is no such limitation provided in the definition of the term "pathogen" in the specification. Further, while the examples provided in the application are representatives of such pathogens, the specification specifically states "It is to be understood that these examples are set forth by way of illustration only, and nothing therein shall be taken as a limitation upon the overall scope of the invention." App, page 12. Further, the Applicant also argues on pages 7 of the Response that "at the very minimum, Applicant's specification teaches and suggests pathogens that can exist in the gastrointestinal tract of an individual." This statement implies that the specification, while it may suggest at a minimum the detection of gastrointestinal tract pathogens, the specification and the claims are not limited to such. Further, the Applicant also argues on page 8 that "the teachings of Applicant's specification provides support for broadly claiming multiple pathogens, in general, and not simply a "particular set" of pathogens." Thus, the Applicant has both argued, and cited the specification in support of the assertion, that the claims are not limited to any particular set of pathogens. In view of this, the Applicant's arguments as to the scope of the term pathogen are not found persuasive.

The Applicant traverses the rejection on the grounds that there is nothing in the specification to limit the scope of the invention to those that are listed, or to any particular set of pathogens. In addition, the Applicant argues that the Examiner has ignored the Declaration submitted by the Applicant demonstrating a "reasonable correlation" between the presence of a plurality of pathogens and the existence of a disorder. These arguments are not found persuasive. First, neither the data in the application nor the Declaration correlate with the scope of what is being claimed. First, as is argued by the Applicant, the data provided do not demonstrate that any combination of pathogens would demonstrate the presence of autism. Second, while the

Applicant appears to show that, in a comparison between the number of autistic patients and presumably healthy non-autistic subject, the autistic patients have a higher likelihood of having at least one of a number pathogenic infections. However, there is no comparison between the numbers of people with these infections in general to those with the infections and autism. Thus, the data does not provide adequate date to demonstrate a correlation between autism and the presence of pathogens, only that the pathogens are more likely to be present in an autistic patient that in a healthy person.

Also, the data presented by application does not demonstrate that there is necessarily a plurality of pathogens present in an autistic subject. In Figure 4 of the application, 3 of the seven autistic patients have only one infection, demonstrating that in just under half of the patients with autism, there is no plurality of infections. Further, as was indicated in the prior actions, other diseases that are associated or caused by multiple pathogens are known in the art. See, prior action, page 10. See also, U.S. PUB 2004/0057962, page 6, paragraph [0061]. The Applicant's disclosure provides no means to distinguish these other disorders from autism. Thus, the data provided demonstrates neither that the presence of multiple pathogens in a person is necessarily indicative of autism, nor that the presence of any combination of multiple infections is indicative of autism as opposed to some other disorder.

Because the Applicant has not established that the presence of multiple pathogens is necessarily associated with autism (i.e. lack of comparison between those with plural infections and those with autism), nor that any combination of pathogens would be indicative of the autism in a subject, the claims exceed the scope of the data presented by the Applicant. The rejection is therefore maintained for the reasons of record and the reasons above.

12. **(Prior Rejection- Maintained)** Claims 1, 2, 7, and 21 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on methods of determining the susceptibility of a person, or diagnosing a person with, a PDD by detecting a multiplicity of pathogenic infections in a person. The claims were rejected because the Applicant has not provided adequate written description for methods of diagnosing autism based on the presence of any combination of pathogens. Because claim 21 has been cancelled from the application, the rejection is withdrawn from this claim.

The Applicant traverses the rejection on the grounds that the rejection is redundant to the enablement rejection above, and on the grounds that the description provides sufficient support for the claimed invention. These arguments are not found persuasive. The rejection of these claims was on the basis that the Applicant has not provided sufficient disclosure to demonstrate possession of the full scope of the claimed invention.

In support of this assertion, the Applicant's attention is drawn to the following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. The case law additionally indicates that "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application." In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973). See also, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth in support). Thus, the court has indicated that where an application is claiming a genus of inventions, and where there is uncertainty in the operability of non-disclosed species in the claimed invention, the Applicant may be found to have not provided adequate information in support of the claims.

In the present case, the claims read on a genus of inventions comprising the diagnosis of autism based on the presence of any combination of pathogens. However, the Applicant has provided only a limited number of pathogens that may be associated with autism. The Applicant has not provided means for determining what other pathogens may be so associated with the disorder, or provided guidance as to such other pathogens, other than the provided studies to "indicate that there are correlations between the development of various disorders and the presence of microorganisms in the digestive tract." Because the Applicant has not provided examples or other evidence to demonstrate possession of the claimed genus wherein autism may be diagnosed by the presence of any combination of pathogens, the rejection is maintained. The

claims of the present invention are not limited to embodiments where the microorganisms are present in the digestive tract.

The Applicant additionally asserts that the rejection should be withdrawn for "at least the same reasons given above in section [(D)] of the Amendment." However, as these arguments were not found persuasive for the reasons provided above, this argument is also not found persuasive.

The rejection is therefore maintained for the reasons provided above, and the reasons of record.

Conclusion

13. No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 7/26/04

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